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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/750,560

12/28/2000

Jaan Noolandi

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10/16/2002

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/16/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/750,560

Applicant(s)

NOOLANDI ET AL.

Examiner

Jeffrey Siew

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2002 .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12, 14, 15 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 7, 13, 16 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

1. The amendment filed 8/6/02 has been entered. The pending claims are **1-20** of which claims **1,9 and 14** are independent claims. The drawings filed 8/6/02 is acknowledged and according to new Office Procedure, the Draftsman will review at the time of allowance.

The response filed 8/6/02 has been fully considered and deemed not persuasive. The response states that Nasu et al do not teach full image at a given time. The term “given time” reads broadly and does not specify or limit to an exact time length. The claim may read on any duration of time. Nasu et al do teach a full image scan of the gel using a full width scanner (see Figure 1 & Figure 5). While Nasu et al scanner does require scanner to scan through the gel, the apparatus does achieve a full image within a given time duration. Moreover, the limitation of plurality of channels would still read on gel electrophoresis in which DNA samples from a well travel through porous channels of the gel. The specification even states that the invention reads on gel electrophoresis (see page 6 lines 1 & 2). The 102 and 103 rejections over Nasu et al are maintained.

Regarding the 103 rejections over Birnbaum and Mathies et al, the response states that the combination of references does not teach plurality of channels and full image at a given instance. The response further states that Mathies does not teach full image scanning and combination of the references would be impermissible hindsight. The rejection is based on the combination of the teachings of the references. Mathies et al do teach scanning a plurality of capillary channels (see abstract and Figure1). (see abstract). Birnbaum et al further teach the advantages of **instantaneous image** of the progress of separation process (see abstract). It would

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have been prima facie obvious to apply Birnbaum et al's full imaging to the plurality of channels in Mathies et al's device in order to increase throughput scanning. As Birnbaum et al suggest application of full image detection to **capillaries** in electrophoretic apparatus. As MPEP 2145 refers "any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's **disclosure such reconstruction is proper.**" *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). The prior art provides sufficient teachings of all limitations and suggestions to properly meet the claimed device. The 103 rejections based on the combination of Birnbaum and Mathies et al are maintained. The response is reminded that the term given time reads probably and would **not be limited** to an instant.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 9, 12, 14,15,17,18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nasu et al (US5,246,866 September 21, 1993).

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Nasu et al teach a DNA sequencing apparatus in which fluorescently labeled fragments are subject to electrophoresis and illuminated and exposed to detection to create an image corresponding to gel (see whole doc. esp. abstract). They teach the apparatus (see Figure 7) with an electrophoresis unit 73 (separation apparatus) with an upper electrode 74a and lower electrode 74b, which applies an electric field to separate fragments and optical sensor 78 (detector) and optical source 71 (illumination means) (see col. 4 line 5). The apparatus contains a gel, which is a polymer solution. The apparatus is attached to processing unit, which can create image corresponding to gel (see Figure 5-7). The light receiving elements are arranged perpendicular to the direction of electrophoresis (see col. 4 line 5). The image represents the same type of the gel (see col. 4 lines 31-37 & figure 2). The detector scans the full width of the array of samples in gel (see figure 7). Detection occurs over several time periods (see col. 7 line 59).

The term full width scanner reads broadly and would encompass the detector in Nasu et al's device.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 5 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nasu et al (US5,246,866 September 21, 1993) in view of

Nasu et al teach a DNA sequencing apparatus in which fluorescently labeled fragments are subject to electrophoresis and illuminated and exposed to detection to create an image

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corresponding to gel (see whole doc. esp. abstract). They teach the apparatus (see Figure 7) with an electrophoresis unit 73 (separation apparatus) with an upper electrode 74a and lower electrode 74b, which applies an electric field to separate fragments and optical sensor 78 (detector) and optical source 71 (illumination means) (see col. The apparatus contains a gel which is a polymer solution. The apparatus is attached to processing unit which can create image corresponding to gel(see Figure 5-7). The light receiving elements are arranged perpendicular to the direction of electrophoresis (see col. 4 line 5). The image represents the same type of the gel (see col. 4 lines 31-37 & figure 2). The detector scans the full width of the array of samples in gel (see figure 7). Detection occurs over several time periods(see col. 7 line 59).

Nasu et al do not teach lithographically etched channels.

Frankel et al teach lithographically etched channels in glass substrates(see col. 3 line 63-65).

One of ordinary skill in the art would have been motivated to apply Frankel et al's lithographically etched channels in glass substrates to Nasu et al's device in order to perform rapid and plurality separations. Frankel et al teach that channels provide for increased number of separations. It would have been prima facie obvious to apply Frankel's etched channels to Nasu et al's device in order to increase the number of samples that would be assayed during a single run.

5. Claims 1-4,6,8-10,12,14,15 &18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al (US5,274,240 Dec, 28, 1993) in view of Birnbaum et al (US5,627,643 May 6, 1997).

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Mathies et al teach the capillary gel electrophoresis for DNA sequencing (see whole document & col. 6 line 6 & col. 6 line 61).

Mathies et al do not full scan imaging.

Birnbaum et al teach a capillary electrophoresis apparatus to separate fluorescence (see whole doc. esp. abstract). They teach an electrophoretic separation using an electric field (separation device) (see col. 1 line 26). They teach thin capillaries (see col. 1 line 29). In Figure 1 they teach a laser which irradiates samples along the capillary (see col.2 line 20). They teach a CCD detector for generating an electronic image of the appearance of the capillary (see col. 2 lines 24-26 & figure 1). The detection is along the direction of migration (col. 3 line 32). They detect over various time intervals (see col.2 line 22).

One of ordinary skill in the art would have been motivated to apply Birnbaum et al's detection device to in order to provide real time detection of the various labels simultaneously. Birnbaum state that that the whole capillary may be examined momentarily allowing for simultaneous detection which provides a quicker evaluation (see col. 1 lines 40-65). It would have been prima facie obvious to apply Birnbaum et al's device to detect in capillary electrophoretic device in order to detect simultaneously and in real time the separation of DNA fragments.

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6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al (US5,274,240 Dec, 28, 1993) in view of Birnbaum et al (US5,627,643 May 6, 1997) in further view of Della Ciana et al (US6,136,612 Oct 24, 2000).

The teachings and suggestions of Mathies et al and Birnbaum et al are described previously.

Mathies et al do not full LED.

Della Ciana et al teach LED for fluorescent illumination in DNA sequencing (see col. 1 line10-11).

One of ordinary skill in the art would have been motivated to apply LED Mathies et al's apparatus in order to illuminate the fluorescent labeled fragments. Della Ciana et al state that LED's are cheaper, it would have been prima facie obvious to apply LEDs in order to provide for cost efficient light source.

SUMMARY

7. Claims 7,13,16, 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. There is no prior art that teach or suggest the claimed method or device with amorphous silicon 2 dimensional image sensor array . Concerning claim 20 there is no prior art that teach or suggest the claimed device where the laser is attached to the rear of the detector.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.


JEFFREY SIEW
PRIMARY EXAMINER

October 14, 2002